

**K970985 WAKO TOTAL BILIRUBIN V**Apr 21, 1997  
34 days to decisionK970985 · Product code: **JFM** · Chemistry  
Source: <https://www.510kdatabase.net/k970985/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Bilirubin (JFM)
Date received	Mar 18, 1997
Decision date	Apr 21, 1997
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wako Chemicals USA, Inc.</b>
Location	Mchenry, IL, US
Contact	TONYA MALLORY
510(k) history	124 submissions · 123 cleared · 1981-2011

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